UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,651	07/12/2001	Hiroyuki Nakane	77670/495	2816

7590 07/18/2005

Judith L Toffenetti
Kenyon & Kenyon
1500 K Street NW
Suite 700
Washington, DC 20005

EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 07/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/902,651	NAKANE ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 08/898,560.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/18/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] Claims 1-32 are pending in the application.

[2] Applicants' amendment to the claims, filed 3/18/2005, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.

[3] Applicants' amendment to the specification, filed 3/18/2005, is acknowledged.

[4] Receipt of an information disclosure statement (IDS), filed 3/18/2005, is acknowledged.

[5] Receipt of a Statement as to Loss of Original Patent stating that the ribboned original patent grant is lost or inaccessible, filed 3/25/2005, is acknowledged.

[6] Receipt of a statement that the sequence listing includes no new matter, filed 3/18/2005, is acknowledged.

[7] Applicants' arguments filed 3/18/2005 are acknowledged. Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

[8] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

[9] It is noted that applicants offered to surrender the original patent upon reissue of a patent in the Declaration filed 7/12/2001 (see item 12 at page 18). This statement is no longer required.

Information Disclosure Statement

[10] With the exception of references 28 and 31, all references cited in the IDS filed 3/18/2005 have been considered by the examiner. A copy of Form PTO-1449 is attached to the instant Office action.

[11] References 28 and 31 have been lined through on Form PTO-1449 as the citations do not satisfy the requirements of 37 CFR 1.98(b)(5). However, as references 28 and 31 were cited during prosecution of the application issued as a patent and MPEP 1406 directs the examiner to consider all references cited in the original prosecution of the patent, references 28 and 31 have been cited by the examiner on an attached Form PTO-892.

Specification/Informalities

[12] The objection to the amendment to the specification filed 7/12/2001 as being in an improper format (¶ [8] of the Office action mailed 9/29/2004) is withdrawn in view of applicants' amendment to the specification in the instant response.

[13] The objection to the title of the specification (¶ [10] of the Office action mailed 9/29/2004) is withdrawn in view of applicants' amendment to said title.

[14] The amendment filed 3/18/2005 is objected to under 35 U.S.C. § 251 because it introduces new matter into the disclosure. 35 U.S.C. § 251 states that no amendment shall introduce new matter into the disclosure of a reissue application of the invention (see M.P.E.P. § 1410). The added material which is not supported by the original disclosure is as follows: "$D_1D_2X_1(X_2X_3)X_4D_3$." See particularly the amendment to

columns 3-5. Originally, the specification disclosed "DDXX(XX)D (wherein X denotes any amino acid, and the *two X's in the parentheses may not be present*)" (emphasis added). Applicants' amendment to the specification alters the positioning of the parentheses such that it encompasses amino acid sequence permutations that are not supported by the original disclosure.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

[15] The objection to claims 1 and 16-32 as being in an improper format (¶ [12] of the Office action mailed 9/29/2004) is withdrawn in view of applicants' amendment to the claims.

[16] The objection to claim 1 as being grammatically incorrect (¶ [13] of the Office action mailed 9/29/2004) is withdrawn in view of applicants' amendment to the claim.

[17] The objection to claims 8, 24, and 25 in the use of an improper sequence identifier (¶ [14] of the Office action mailed 9/29/2004) is withdrawn in view of applicants' amendment to the claims.

[18] The "warning" that claims 24-25 will be objected to under 37 CFR 1.75 as being substantial duplicates if claims 8-9 are found allowable is moot in view of applicants' amendment to claims 8-9.

[19] The objection to claim 16 as being in improper form (¶ [16] of the Office action mailed 9/29/2004) is withdrawn in view of applicants' amendment to the claim.

[20] The objection to claim 17 as being grammatically incorrect (¶ [17] of the Office action mailed 9/29/2004) is withdrawn in view of applicants' amendment to the claim.

Claim Rejections - 35 USC § 112, Second Paragraph

[21] The rejection of claims 1-32 as being confusing in view of the evidence of Figure 3 is maintained for the reasons of record (¶ [18] part [a] of the Office action mailed 9/29/2004) and the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the claims "clearly recite" that the mutant prenyl diphosphate synthase has the ability to "synthesize[] farnesyl diphosphate which is shorter than prenyl diphosphate synthesized by a corresponding wild-type prenyl diphosphate synthase." Referring to the results of thin layer chromatography of Figure 3, applicants argue the main spot of the wild-type (SacGGPS) is GGOH, while the main spot for the mutant enzymes is FOH. Applicants note the FOH is shorter than the GGOH. Applicants argue the issue is the product selectivity or specificity of the enzyme reaction, which is relative, not absolute. Applicants further note that the term "prenyl diphosphate" is a generic term encompassing geranylfarnesyl-, farnesyl-, geranylgeranyl-, farnesyl-, and geranyl-diphosphate.

Applicants' argument is not found persuasive. In view of applicants' argument, it would appear that applicants intend for the term "synthesize[] farnesyl diphosphate which is shorter than prenyl diphosphate synthesized by a corresponding wild-type prenyl diphosphate synthase" to be interpreted as the mutant synthesizes *more* farnesyl

diphosphate than a corresponding wild-type prenyl diphosphate synthase. However, this is clearly not what the term says and the term has not been interpreted as such. Applicants do not dispute that the wild-type enzyme has the ability to produce farnesyl-diphosphate, corresponding to FOH in Figure 3. Also, applicants acknowledge that the term "prenyl diphosphate" encompasses farnesyl-diphosphate. As noted in a previous Office action, there is no indication in Figure 3 that the farnesyl-diphosphate produced by the wild-type enzyme is any shorter than the farnesyl-diphosphate (represented by FOH in Figure 3) produced by the mutants. As such, it is unclear as to the intended meaning of the term "wherein said mutant prenyl diphosphate synthase synthesizes farnesyl diphosphate which is shorter than prenyl diphosphate synthesized by a corresponding wild-type prenyl diphosphate synthase" when the prenyl diphosphate synthesized by a corresponding wild-type prenyl diphosphate synthase is farnesyl-diphosphate. Clarification of the term is requested.

[22] The rejection of claims 1 (claims 2-16 rejected as being dependent therefrom) and 17 (claims 18-32 rejected as being dependent therefrom) as being unclear in the recitation of "an amino acid between D1 and the amino acid residue at the fifth position upstream of D1" (¶ [18] part [b] of the Office action mailed 9/29/2004) is withdrawn in view of applicants' clarification of the term. Applicants clarify the meaning of the term as an amino acid "between and not including" D1 and the amino acid residue at the fifth position upstream of D1.

[23] The rejection of claims 1 (claims 2-16 rejected as being dependent therefrom) and 17 (claims 18-32 rejected as being dependent therefrom) as being indefinite in the

recitation of "region II" is maintained for the reasons of record (¶ [18] part [c] of the Office action mailed 9/29/2004) and the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the term "region II" is well-known in the art and a person of ordinary skill would understand it. Applicants assert "region II" is "the second region with high amino acid sequence homology between various prenyl diphosphate synthases."

Applicants' argument is not found persuasive. Applicants refer to Figure 1 of the drawings for guidance in interpreting the term "region II." Figure 1 shows an alignment of various geranylgeranyl diphosphate synthases from various sources. It is noted that even within this alleged "region with high amino acid sequence homology between various prenyl diphosphate synthases," there is significant variation among the sequences of "region II." It is not clear from applicants' argument as to whether the "region II" is meant to be limited to a particular sequence shown in Figure 1, all of the sequences that appear in Figure 1, or if the term is meant to encompass additional undisclosed "region II" amino acid sequences. If the term is meant to be limited to those that are disclosed in Figure 1, applicants are requested to so state and clarify the record. If not, applicants are requested to so state and clarify the term by identifying those distinguishing characteristics of the amino acid sequences that are meant to be encompassed by the term such that a skilled artisan would recognize that the "aspartic acid-rich domain" was present in "region II" or some other region of a polypeptide. In the absence of such clarifying remarks, a skilled artisan would have no way of determining

whether the "aspartic acid-rich domain" occurs in "region II" of a polypeptide or some other region or domain of a polypeptide.

[24] The rejection of claims 2 (claim 16 rejected as being dependent therefrom) and 18 as being indefinite in the recitation of "wild type prenyl diphosphate synthase" (¶ [18] part [d] of the Office action mailed 9/29/2004) is withdrawn in view of the amendment to the claims.

[25] The rejection of claims 2 (claim 16 rejected as being dependent therefrom) and 18 as being confusing (¶ [18] part [e] of the Office action mailed 9/29/2004) is withdrawn in view of the amendment to the claims.

[26] The rejection of claim 4 (claim 16 rejected as being dependent therefrom) as being unclear in the recitation of "homodimer-type" (¶ [18] part [f] of the Office action mailed 9/29/2004) is withdrawn in view of the amendment to claim 4.

[27] The rejection of claims 5-6 (claim 16 rejected as being dependent therefrom) and 21-22 as being indefinite in the recitation of "derived from" (¶ [18] part [g] of the Office action mailed 9/29/2004) is withdrawn in view of the amendment to the claims.

[28] The rejection of claims 7 (claim 16 rejected as being dependent therefrom) and 23 as being unclear in the recitation of the relative term "thermostable" is withdrawn in view of the amendment to the claims.

[29] Claim(s) 2-3, 16, and 18-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

[a] Claims 2 (claim(s) 16 dependent therefrom) and 18 are unclear in the recitation of "an enzymatic activity in the synthesis of prenyl diphosphate." It is unclear from the specification and the claims as to the scope of enzymatic activities that are encompassed by the term "an enzymatic activity in the synthesis of prenyl diphosphate." This term encompasses not only those enzymatic activities that are directly involved in prenyl diphosphate synthesis, but also those enzymatic activities involved in the synthesis of the precursors of prenyl diphosphates. It is suggested that applicants clarify the meaning of the claims.

[b] Claims 3 and 19 limit the reaction product of "the prenyl diphosphate synthase" to farnesyl diphosphate. However, it is unclear as to whether the term "the prenyl diphosphate synthase" refers to the mutant, wild-type, or mutant and wild-type prenyl diphosphate synthase of claim 1. It is suggested that applicants clarify the meaning of the term.

Claim Rejections - 35 USC § 112, First Paragraph

[30] The new matter rejection of claim(s) 1-32 under 35 U.S.C. 112, first paragraph, (¶ [19] of the Office action mailed 9/29/2004) is withdrawn in view of applicants' amendment to the claims to replace "prenyl" with "farnesyl."

It is noted that MPEP § 2163 states, "when filing an amendment an applicant should show support in the original disclosure for new or amended claims" and "[i]f the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or

amended claim must be rejected under 35 U.S.C. 112, para. 1, as lacking adequate written description." While applicants have failed to "show support" for this amendment (or any other amendment to the claims) in accordance with the MPEP, the examiner can find support for this particular amendment at page 10, lines 33-36 of the specification of application 08/898,560.

[31] The new matter rejection of claim(s) 17-32 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record (¶ [20] of the Office action mailed 9/29/2004) and the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the rejection has been overcome by amendment, namely to cancel the language, "and X_2 and X_3 are each optionally independently present in the aspartic acid rich domain."

Applicants' argument is not found persuasive. 35 U.S.C. 251 makes clear that "[n]o new matter shall be introduced into the application for reissue." Also, as noted above, MPEP § 2163 requires that applicants "show support" for a claim amendment. However, applicants have failed to show support for the limitation of a "domain having the sequence $D_1D_2X_1(X_2X_3)X_4D_3$." Applicants are invited to show support for this limitation in the original specification, claims, and/or drawings as filed.

[32] Claim(s) 7, 16, and 23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 7 (claim(s) 16 dependent therefrom) and 23 recite the newly added limitation, "the [mutant] prenyl diphosphate synthase is more thermostable than corresponding wild-type prenyl diphosphate synthase."

35 U.S.C. 251 makes clear that "[n]o new matter shall be introduced into the application for reissue." Also, MPEP § 2163 states, "when filing an amendment an applicant should show support in the original disclosure for new or amended claims" and "[i]f the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, para. 1, as lacking adequate written description".

Applicants have failed to show support for the amendment and the examiner can find no such support. Applicants are invited to direct the examiner to such support in the original specification, claims, and/or drawings.

[33] Upon further consideration, the written description rejection of claim(s) 8-9, 11-14, 24-25, and 27-30 under 35 U.S.C. 112, first paragraph, (¶ [21] of the Office action mailed 9/29/2004) is withdrawn. The structure of the genus of polypeptides of claims 8-9 and 24-25 is limited to specifically defined variants of SEQ ID NO:1, i.e., SEQ ID NO:1 with amino acid substitution at position 77, 78, 80, and/or 81 or a variant with an insert of one or more amino acids between positions 84 and 85 of SEQ ID NO:1. Thus, the genus of mutants of claims 8-9 and 24-25 share structural features that are common to all members of the genus wherein the structural feature is a substantial portion of the genus. The genus of mutant polypeptides of claims 8 and 24 all share the functional

limitation of the polypeptide of claim 1, i.e., synthesizes farnesyl diphosphate that is shorter than prenyl diphosphate synthesized by a corresponding wild-type prenyl diphosphate synthase. As such, it is the examiner's position that the mutants of claims 8-9 and 24-25 meet the written description requirements of 35 U.S.C. 112, first paragraph. Similar reasoning applies to the nucleic acids of claims 11-13 and 27-29. As such, it is the examiner's position that the claimed polypeptides and encoding nucleic acids meet the written description requirements of 35 U.S.C. 112, first paragraph.

As a point of clarification, it is noted that claims 12 and 28 are drawn to RNAs that are transcribed from the DNAs of claims 11 and 27, respectively. The examiner has interpreted claims 12 and 28 as being RNAs that are identical to the DNAs of claims 11 and 27, respectively, with the exception that the base T in the DNAs of claims 11 and 27 is replaced with U in the claimed RNAs. If this is not applicants' intended interpretation of claims 12 and 28, applicants are requested to so state and clarify the record.

[34] The written description rejection of claim(s) 1-7, 10, 15-23, 26, and 31-32 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record (¶ [21] of the Office action mailed 9/29/2004) and the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the examiner's reliance on Lilly is misplaced. According to applicants, the Lilly Court held that a written description of a *DNA* requires precise definition and that claims 1-10 and 17-26 are drawn to enzymes, not DNA. Applicants argue that the five disclosed representative species of mutants are representative of the genus of claimed enzymes such that a skilled artisan would be able to reconstruct any mutant synthase from the five representative species.

Applicants' argument is not found persuasive. In response to applicants' argument that the examiner's reliance on Lilly is misplaced, it is noted that the Court in University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 held that, while the Lilly case was related to genetic material, the distinction is irrelevant as the statute applies to all types of inventions, stating that "[w]e see no reason for the rule to be any different when non-genetic materials are at issue." As such, Lilly clearly applies to the polypeptides of claims 1-7, 10, 17-23, and 26.

In response to applicants argument that a skilled artisan can reconstruct all members of the genus of claimed proteins and nucleic acids encoding therefor, the examiner maintains the position that the minimal common structural feature shared by all members of the genus of claimed polypeptides and nucleic acids does not constitute a substantial portion of the genus. Using claim 1 as an example, the only structural feature required by all members of the claimed genus is the sequence $D_1D_2X_1X_2(X_3X_4)D_3$ in "region II," wherein X_3X_4 are not even required to be in the sequence. Outside of this minimal structural feature, the remainder of the structure of the polypeptide is completely undefined. One of skill in the art would recognize that such a minimal sequence would not possess the recited farnesyl diphosphate synthase enzymatic activity. Thus, in order for the polypeptides to exhibit the recited enzyme activity, it is necessary to add amino acids to the N- and/or C-terminal ends of the recited sequence to reconstruct a polypeptide that would properly fold into an enzymatically active polypeptide. In this case, the members of the genus are widely variant with respect to their structures outside of the recited sequence. The five

representative disclosed species, which appear to all have identical amino acid sequences outside of the recited aspartic acid-rich domain, fail to represent the variation among all members of the genus, and consequently fail to describe all members of the claimed genus of proteins and nucleic acids.

[35] The scope of enablement rejection of claims 1-32 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record (¶ [22] of the Office action mailed 9/29/2004) and the reasons stated below.

RESPONSE TO ARGUMENT: Applicants argue the five mutant examples are representative of the genus of mutant enzymes such that a skilled artisan could predict other mutants as encompassed by the claims. According to applicants, it would not constitute undue experimentation to make and use all enzymes as encompassed by the claims.

Applicants' argument is not found persuasive. In a previous Office action, the examiner presented a detailed analysis of the relevant factors of In re Wands, providing reasoning, including prior art references, in support of the instant rejection. In response, applicants allege a skilled artisan could make the full scope of claimed enzymes using the five working examples for guidance. It is noted that applicants have provided no objective or scientific reasoning in support of their position.

As noted in a previous Office action, the enzymes of claims 1-7, 10, 15-23, 26, and 31-32 encompass a vast number of mutant prenyl diphosphate synthase polypeptides having the minimal structural features recited in claims 1 and 17. The specification discloses only five working examples of the claimed polypeptides and fails

to provide guidance for making other mutant enzymes within the scope of the claims. Further, the prior art references of Branden and Witkowski et al., the teachings of which are undisputed by applicants, support a high level of unpredictability in the art. In view of the broad scope of the claims, the lack of guidance and working examples, the high level of unpredictability as supported by the prior art, and the significant amount of trial and error experimentation required, which was not typically practiced at the time of the invention, the specification fails to enable the full scope of the claimed invention without undue experimentation. Further, even if the mutants were limited to specific structures as in claims 8 and 9 (claim(s) 11-14 dependent therefrom) and 24-25 (claim(s) 27-30 dependent therefrom), (limited to specific mutants of SEQ ID NO:1, i.e., SEQ ID NO:1 with mutation at position 77, 78, 80, 81, and/or 84 or SEQ ID NO:1 with one or more amino acids inserted between positions 84 and 85), it is noted that the mutants are required to have the function of synthesizing farnesyl diphosphate which is shorter than prenyl diphosphate synthesized by a corresponding wild-type prenyl diphosphate synthase. As noted above (¶ [20]), the term "prenyl diphosphate" is a generic term encompassing geranylfarnesyl-, farnesyl-, geranylgeranyl-, farnesyl-, and geranyl-diphosphate. While the specification provides evidence that the mutants can produce relatively greater amounts of farnesyl diphosphate as compared to the corresponding wild-type, there is no indication in the specification that the mutants have the ability to synthesize farnesyl diphosphate that is shorter than the farnesyl diphosphate synthesized by a corresponding wild-type enzyme (see particularly Figure 3).

As such, the specification fails to enable the full scope of the claimed invention.

Double Patenting Rejection(s)

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

[36] Claims 1-6, 8-10, 17-22, and 24-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 4 of US Patent 5,807,725 (the '725 patent). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-6, 8-10, 17-22, and 24-26 are generic to all that is recited in claims 1 and 4 of the '725 patent. That

is, claims 1 and 4 of the '725 patent fall entirely within the scope of claims 1-6, 8-10, 17-22, and 24-26 of the instant application. In other words, claims 1-6, 8-10, 17-22, and 24-26 of the instant application are anticipated by claims 1 and 4 of the '725 patent. Specifically, claims 1 and 4 of the '725 patent are drawn to a mutant Sulfolobus acidocaldarius geranylgeranyl diphosphate synthase having a mutation of SEQ ID NO:1 to replace Phe at position 77 with Ser.

[37] Claims 11, 13-15, 27, and 29-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of US Patent 5,882,909 (the '909 patent). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 11, 13-15, 27, and 29-31 are generic to all that is recited in claims 1-4 of the '909 patent. That is, claims 1-4 of the '909 patent fall entirely within the scope of claims 11, 13-15, 27, and 29-31 of the instant application. In other words, claims 11, 13-15, 27, and 29-31 of the instant application are anticipated by claims 1-4 of the '909 patent. Specifically, claims 1-4 of the '909 patent are drawn to a gene encoding a mutant Sulfolobus acidocaldarius geranylgeranyl diphosphate synthase having a mutation of SEQ ID NO:1 to replace Phe at position 77

with Ser, an expression vector comprising said gene, a host cell transfected with said expression vector, and a process for producing the mutant enzyme.

Conclusion

[38] Status of the claims:

- Claims 1-32 are pending.
- Claims 1-32 are rejected.
- No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Thursday and alternate Fridays from 7:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (571) 273-8300. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID J. STEADMAN, PH.D.
PRIMARY EXAMINER